Further, new claim 19 has been added. Support for claim 19 is found in the specification, in particular on page 15, lines 24-26.

Claims 2-11 and 15-19 are pending in the present application. Claims 2-8, 15 and 18-19 are directed to a fusion protein, claim 9 is directed to a hybrid DNA, claim 10 is directed to a recombinant vector, claim 11 is directed to a recombinant Avipox virus, claim 16 is directed to a recombinant live vaccine and claim 17 is directed to a trivalent live vaccine.

As a preliminary, in the Office Action Summary, it is indicated that claims 1 and 12-13 are withdrawn from consideration.

It is believed that this indication is erroneous, as it is acknowledged in the body of the Office Action that claims 1 and 12-13 have been canceled.

Further, in the Office Action, claims 2-11 and 14-17 are rejected under 35 U.S.C. 112, first paragraph for lack of written description and lack of enablement. It is alleged in the Office Action that claim 14 is indefinite because the specification does not teach how to make additional polypeptides derivatives. Specifically, it is alleged that the term "derived from" is vague and indefinite in the absence of definition of derivation or indication of requisite amount of retained qualities or characteristics. Also, it is alleged that claims 9-12 recite DNA coding for the fusion protein but "no specific DNA sequence is recited."

Reconsideration and withdrawal of the rejection is respectfully requested. Claim 14 has been amended and rewritten as new claim 18 which recites that the polypeptide derived from Herpesvirus outer membrane protein has at least one epitope of Herpesvirus outer membrane protein. It is submitted that the present specification clearly defines and exemplifies a polypeptide derived from Herpesvirus outer membrane protein in that the polypeptide has at least one epitope

of Herpesvirus outer membrane. In particular, a person of ordinary skill in the art would understand how to select appropriate sequences and prepare a polypeptide which has the appropriate epitope as recited in claim 18. Therefore, present claim 18 is enabled and the written description in the application is sufficient with respect to claim 18.

In addition, with respect to claim 19, it is submitted that the recitation that the polypeptide has at least 90% homology to a native Herpesvirus outer membrane protein provides an additional guidance to further enable a person of ordinary skill in the art. Therefore, for this reason alone, claim 19 is enabled and the written description is sufficient with respect to claim 19.

Further, with respect to claims 9-12, it is submitted that the specific amino acid sequence of the fusion protein is not recited in claims 9-12 because this specific sequence depends on the amino acid sequence of each of the ligated polypeptides defined in claim 1. It is submitted that the DNA sequence corresponding to many such polypeptides is known, as mentioned in the specification, or can be determined by conventional methods. Once the amino acid sequence of the fusion protein is known, a person of the art is able to determine immediately without undue experimentation an appropriate DNA sequence encoding such fusion protein. Therefore, present claims 9-12 are enabled and the written description in the application is sufficient with respect to claims 9-12.

In view of the above, it is submitted that the written description and enablement rejections should be withdrawn.

Next, in the Office Action, claims 2-11 and 14-17 are rejected under 35 U.S.C. 112, second paragraph, as indefinite. First, it is alleged in the Office Action that claim 14 "does not reasonably provide proper basis for the use of antibody-antigen reactions" and that claim 14 is

supported by "neither the specification nor any of the claims." Second, it is alleged that claims 16-17 do not recite a specific protein size, sequence or amino acid fragment, so that there is no teaching in the specification that a peptide derived from a Herpes outer membrane protein will be effective as part of a vaccine.

Reconsideration and withdrawal of the rejection is respectfully requested. First, with respect to claim 14, it is submitted that claim 14 has been amended and rewritten as new claim 18 which recites that the polypeptide causing an antibody-antigen reaction with Mg immune serum or Mg infected serum has an epitope of Mg polypeptide showing antigenicity. Further, the recitation in claim 14 which is objected to is literally supported in the specification on page 6, lines 13-15, and the added recitation is also supported on page 6, lines 24-25.

Second, with respect to claims 16-17, it is submitted that the vaccine of claim 16 is directed to Mg, not Herpesvirus. The present inventors have taught and exemplified for the first time that inoculation with the Avipox virus containing DNA coding for the fusion protein results, not only in antibody production, but also in protection against subsequent reinfection. Further, the specification clearly teaches the selection of an appropriate Mg-derived antigenic polypeptide and herpes virus outer membrane-derived polypeptide, the function of each polypeptide, and the insertion of a corresponding coding DNA sequence in an Avipox virus, and clearly demonstrates by way of examples the immunization which results from inoculation. As a result, a person of ordinary skill in the art would find appropriate guidance in the application on how to prepare the recombinant virus so as to obtain an effective action against Mg.

In addition, dependent claims 2-8 further define the Herpes-derived polypeptide, and in particular, claim 4 defines polypeptides used in the examples of the specification, so that claims 16-17 as dependent on any of claims 2-8 are enabled.

In view of the above, it is submitted that the indefiniteness rejections should be withdrawn.

Next, in the Office Action, claims 2-10, 14-15 and 17 are rejected under 35 U.S.C. 103(a) as obvious over WO 94/23019 which names Sajto as an inventor ("**Sajto**") in view of Yoshida et al., Virology, Vol. 200 (1994) ("**Yoshida**"); and claims 11 and 16 are rejected under 35 U.S.C. 103(a) as obvious over **Sajto** in view of **Yoshida**, and further in view of ("**Yangida**").

It is alleged in the Office Action that **Sajto** discloses the subject matter of claims 1-10 and 13 except the polypeptide derived from a Herpes outer membrane protein, and that **Yoshida** "suggests that FPV is a good candidate for an MDV vaccine and that gB is an important target for the host immune response," so that it would have been obvious to use the polypeptide derived from **Yoshida** with the fusion protein of **Sajto**.

Also, with respect to claims 11-12, it is additionally alleges that **Yangida** "teaches that recombinant Avipoxvirus genes are effective as vaccine," so that it would have been obvious to use the recombinant Avipox virus of **Yangida** with the fusion polypeptide of **Yoshida** and **Sajto**.

In answer to the arguments made in the response to the first Office Action that (i) **Sajto** is silent as to the membrane anchoring sequence of Herpesvirus, (ii) **Sajto** does not test antigenicity *in vivo*, and (iii) there is no suggestion to combine the references, it is alleged in this Office Action that the features in (i) and (ii) are not recited in the claims, and the suggestion in (iii) may be provided by the references or by "knowledge generally available to one of ordinary skill in the art."

In addition, it is alleged that the declaration by Mr. Saitoh is not convincing because it is directed to proteins other than the fusion protein as recited in the claims.

The rejection is respectfully traversed for the following reasons.

As a preliminary, it is submitted that, contrary to the position set forth in the Office Action in answer to arguments made in the response to the first Office Action, (i) claim 14 - now claim 18 - does recite a polypeptide related to Herpesvirus outer membrane protein whereas **Sajto** is silent as to this feature, and (ii) the argument that **Sajto** does not test antigenicity *in vivo* was made to show the defective teaching in **Sajto**, which confirms the lack of suggestion or motivation in **Sajto** to test a polypeptide related to Herpesvirus outer membrane protein, so that this argument remains effective.

Further, it is submitted that the scope and the object of the declaration has been misconstrued. The declaration was submitted to show that the proteins of **Sajto**, wherein the polypeptide ligated to the Mg-derived antigenic polypeptide is not derived from Herpesvirus, have no antigenicity *in vivo*. Thus, the tests reported in the declaration appropriately focus on the proteins of **Sajto**, not the fusion protein of the present invention.

Specifically, the declaration was submitted so as to provide evidence confirming that a person of ordinary skill in the art, confronted to the problem of finding a candidate for antigenicity, would not be motivated to use the NDV proteins of **Sajto** or any other signal membrane anchor of a virus that infects birds, because that person would be aware of their lack of effectiveness *in vivo* as demonstrated in the declaration. As a result of the lack of antigenicity *in vivo* of the proteins of **Sajto**, as evidenced in the declaration, there would have been no

motivation to combine **Sajto** with **Yoshida**, because there would have been an expectation of a similar lack of antigenicity *in vivo*.

In contrast, the products of the presently claimed invention show a strong antigenicity *in vivo,* as reported in the present specification, in the same conditions as the *in vivo* testing of the proteins of **Sajto** reported in the declaration. It is submitted that this result, using a Herpesvirus-derived polypeptide, as recited in the present claims, is clearly unexpected based on the teaching of **Sajto**.

In addition, in **Sajto**, a signal membrane anchoring region of HN protein is used, which results in antigen being provided on the surface of a cell membrane. In contrast, in the presently claimed invention, at least a portion of the antigens separate from the cell membrane to cause a phenomena of "secretion." This result is also unexpected based on the teaching of **Sajto**.

In view of the above, the present claims are not obvious over any combination of the cited references. Therefore, it is submitted that the prior art rejections should be withdrawn.

In conclusion, the invention as presently claimed is patentable. It is believed that the claims are in allowable condition and a notice to that effect is earnestly requested.

In the event there is, in the Examiner's opinion, any outstanding issue and such issue may be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number listed below.

In the event this paper is not considered to be timely filed, the Applicants hereby petition for an appropriate extension of the response period. Please charge the fee for such extension and any other fees which may be required to our Deposit Account No. 01-2340.

Respectfully submitted,

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